

### **REMARKS**

The above listed claim amendments along with the following remarks are fully responsive to the Office Action set forth above.

In that Office Action, the Examiner rejected claims 18 and 32-41. By this Amendment and Response, the Applicant hereby submits terminal disclaimers to obviate rejections on the ground of nonstatutory obviousness-type double patenting. Additionally, Claim 18 has been amended to more particularly point out and distinctly claim the subject matter of the present invention. Support for this amendment can be found throughout the specification, and thus no new matter has been added. Claims 18 and 32-41 are currently pending.

#### **Double Patenting**

The Examiner rejected claims 18, 32, 34-37, 40 and 41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent 6,537,203. Claims 18, 32, 34 and 36-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 30, 40 and 41 of U.S. Patent 6,564,094. Claims 33 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 30, 40 and 41 of U.S. Patent 6,564,094 in view of U.S. Patent 6,567,699.

Without acquiescing and reserving all rights, submitted herewith are terminal disclaimers relating to each of the above-identified U.S. patents. Withdrawal of the rejections on the ground of non-statutory obviousness-type double patenting is respectfully requested.

#### **Claims Rejections – 35 USC § 102(b)**

Claims 18, 32 and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,533,958 (the “Wilk Patent”). Briefly, the Office Action asserts that the Wilk Patent discloses, among other things, placing on a heart a device comprising a biocompatible material configured to engage a surface of the heart to constrain circumferential expansion of

the heart. Without acquiescing and reserving all rights, by this Amendment and Response, Claim 18 is amended to more particularly point out and distinctly claim the subject matter of the present invention, and to distinguish the claimed invention from the Wilk Patent and other prior art of record.

Amended Claim 18 recites a method for treating cardiac disease of a heart, the method comprising, in part, placing a device on the heart, the device comprising compliant biocompatible material configured to engage a surface of the heart to passively constrain circumferential expansion of the heart. The claimed method further comprises passing an electrical current to the heart with the current selected to apply an electrical therapy to the heart.

In contrast, the Wilk Patent is directed to an “intrapericardial assist device and method” for resuscitating a stopped heart as an alternative to conventional CPR techniques. The device includes an electrode carrying balloon (60) having an inwardly facing contact surface (62) and an array of electrode wires (64) disposed on the contact surface (60). As disclosed, the balloon can be inflated to maintain the contact surface of the balloon in engagement with the heart during a “cardiac jump start.” The Wilk Patent further discloses inflating the balloon forcefully in synchronism with heart contractions, thereby imparting “a compressive pressure on the heart to thereby increase pumping action” See Col. 6, lines 40-59. The specification discloses “inflation componentry” and a control unit (80) for inflating the balloon at a “predetermined periodicity” and/or in synchronism with heart contractions. See Col. 5, line 61 to Col. 6, line 12.

For at least two reasons, the Applicant respectfully asserts that the claimed method including placing on a heart a device comprising biocompatible material configured to passively constrain circumferential expansion of the heart, in combination with passing an electrical current to the heart, is not disclosed or suggested by the Wilk Patent. First, unlike the device recited in amended Claim 18, the assist device of the Wilk Patent requires elaborate inflation componentry and controls for regulating inflation of the balloon. The device of the Wilk Patent is effectively an active assist device, and is therefore far different than the device

recited in amended Claim 18, which is configured to passively constrain circumferential expansion of the heart.

Second, the Applicant respectfully disagrees with the assertion in the Office Action that the Wilk Patent discloses a device configured to constrain circumferential expansion of the heart. The Applicant is unable to find any teaching or suggestion in the Wilk Patent that the device constrains circumferential expansion of the heart. Rather, the balloon device of the Wilk Patent operates to maintain the disclosed electrode wires in contact with the heart and to apply a “compressive pressure” on the heart to “increase pumping action.” As understood by the Applicant, this “compressive pressure” is achieved by inflating the disclosed balloon “forcefully in synchronism with a heart contraction.” Nothing in the Wilk Patent teaches or fairly suggests constraining circumferential expansion of the heart. To the contrary, if anything, the Wilk Patent teaches that the disclosed balloon is deflated and/or depressurized between contractions of the heart (i.e., as the heart expands during diastolic filling), and thus does not constrain circumferential expansion of the heart when so depressurized.

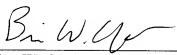
Furthermore, the claimed method has significant advantages over the device and method of the Wilk Patent. For example, the passive device as claimed requires none of the complicated “inflation componentry” and control equipment necessary for the inflatable balloon assist device of the Wilk Patent. Furthermore, in addition to constraining undesirable circumferential enlargement of the heart, the device of the claimed invention also advantageously treats valvular disorders. See, e.g., Page 14 at Lines 8-24. The foregoing is neither taught nor suggested by the Wilk Patent.

For at least these reasons, amended Claim 18 is believed to be patentable over the Wilk Patent. Additionally, because claims 32 and 34-41 depend, either directly or indirectly from Claim 18, those claims are believed to be patentable over the Wilk Patent for at least the same reasons. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

All pending claims are believed to be in condition for allowance. The Applicant respectfully requests that a Notice of Allowance be issued in this case.

Respectfully submitted,

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